

REMARKS/ARGUMENTS

In this Amendment Under 37 C.F.R. § 1.111 ("Amendment"), Applicant amends the specification and Abstract of the Disclosure, as discussed below. Applicant also amends claim 1 to recite "wherein the second part further includes a stiffer portion configured to be at least partially disposed in the urethra of the sexual organ of the second person", amends claim 2 to recite "wherein the material that is designed to rupture upon ejaculation of the second person is a membrane", and amends claims 3 and 4, all in order to better define the claimed invention. Additionally, Applicant makes other amendments to claim 1 in order to improve clarity. Further, Applicant adds new claims 9-20. No new matter is introduced.

Prior to entry of the Amendment, claims 1-8 were pending in the application. After entry of the Amendment, claims 1-20 are pending in the application.

In the Office Action, the Examiner objected to the specification; objected to the Amendment After Final Under 37 C.F.R. § 1.116 ("Amendment After Final") filed on September 27, 2007, under 35 U.S.C. § 132(a); rejected claims 1 and 8 under 35 U.S.C. § 112, ¶ 1 (enablement); rejected claims 2 and 8 under 35 U.S.C. § 112, ¶ 1 (written description); rejected claims 1-4 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,458,114 to Herr ("Herr"); and rejected claims 5-8 under 35 U.S.C. § 103(a) as being unpatentable over Herr.

Abstract of the Disclosure

Applicant amends the Abstract of the Disclosure by canceling the previous version of the Abstract and replacing it with the attached Abstract of the Disclosure, as discussed in the Federal Register at Vol. 68, No. 125, p. 38616 (Monday, June 30, 2003).

Objection to the Amendment After Final

Applicant notes that the originally filed claims are part of the original disclosure. Applicant also notes that originally filed claim 1 recited: "A device for preventing transmission of body fluids between two persons, at least one of whom is male, during sexual relations, said device is formed of an elastic material and said device has an inner side (3), at least a part of which is coated with a glue provided to fix said device to the man's sexual organ, characterized in that at least a second part of said device consists of a material which is provided to rupture upon ejaculation" (emphasis added).

Additionally, Applicant notes that the new paragraph added by the Amendment After Final at p. 6/l. 34 recites: "The device 1 or device 7 may prevent transmission of body fluids between two persons, at least one of whom is male, during sexual relations. The device 1 or device 7 is formed of elastic material and has an inner side, at least a part of which is coated with glue provided to fix the device to the man's sexual organ. At least a second part of the device 1 or device 7 includes a material that is provided to rupture upon ejaculation" (emphasis added).

Because the objected-to language of the Amendment After Final is a virtual quotation from originally filed claim 1, Applicant submits that it is not new matter.

As a result, Applicant submits that this discussion obviates the objection to the Amendment After Final and requests that the objection be withdrawn.

Objection to the Specification

Because the objection to the specification appears to parallel the objection to the Amendment After Final, Applicant submits that the discussion above also obviates the objection to the specification and requests that the objection be withdrawn.

Rejection Under 35 U.S.C. § 112, ¶ 1 (Enablement)—Claims 1 and 8

Applicant submits that the specification would enable one of ordinary skill in the art to make and use the claimed invention without undue experimentation.

Regarding claim 1, Applicant submits that devices for preventing transmission of bodily fluids during sexual relations have a long history. Almost all of that history involves the use of material that is designed not to rupture upon ejaculation. A not-insignificant part of that history involves failure, material that ruptured upon ejaculation even though it was designed not to do so. Based on that history, indentifying a material designed to rupture upon ejaculation is not difficult. Thus, Applicant submits that one of ordinary skill in the art would understand—given Applicant's enabling disclosure (e.g., p. 5/ll. 10-30, originally filed claims 1 and 2, and Figs. 1a and 1b)—how to

include a material that is designed to rupture upon ejaculation in the second part without undue experimentation.

Regarding claim 8, Applicant submits that two-component glues are widely known. Thus, one of ordinary skill in the art would understand such two-component glues, including suitable first and second components for use in the claimed invention. This is particularly true in light of the fact that the specification states: "The glue is dissolved by dipping the penis in or coating it with a solvent, for example dimethyl ketone, methanol or ethanol" (specification, p. 6/ll. 16-18), providing specific examples of possible solvents for such two-component glues.

Applicant also notes that the Office Action states:

[I]t would have been obvious to one skilled in the art at the time of the invention to have used a skin glue, as it is sometimes called in the field, as the second component to be administered on the user's penile glans such that [it] fix[es] the penile cap device to the user's penile glans (10).

Office Action, p. 6.

Applicant submits that this admission completely contradicts the Office Action's allegation that "one skilled in the art would not be enabled to make this second component of the glue . . . since the material of the second component is not named". Id., p. 3.

Applicant submits that this discussion obviates the Examiner's rejection of claims 1 and 8 under 35 U.S.C. § 112, ¶ 1.

Rejection Under 35 U.S.C. § 112, ¶ 1 (Written Description)—Claims 2 and 8

As discussed above, Applicant amends the specification to add the following language that parallels the recitation of originally filed claim 2: “Second part 4 may include a first, stiffer portion, provided to be at least partially situated in the man’s spermatic duct, and a second, more brittle portion provided to burst upon ejaculation. When the second, more brittle portion bursts upon ejaculation, the man’s seminal fluid may flow freely through device 1.”

Applicant notes that originally filed claim 2 recited (emphasis added): “The device as claimed in claim 1, wherein said second part comprises a first, stiffer part, provided to at least partially be situated in the man’s spermatic duct, and a second, more brittle part provided to burst upon ejaculation, thereby enabling the man’s seminal fluid to flow freely through said device.”

As a result of this first amendment to the specification (based at least on originally filed claim 2), Applicant submits that the specification provides written description support for the recitation “a more brittle portion”.

As discussed above, Applicant amends the specification to add the following language that parallels the recitation of originally filed claim 8: “As discussed above, the glue may be of the two-component type, with a first component and a second component. Inner side 3 may be coated with the first component that is non-adhesive. A part of the man’s sexual organ may be coated with the second component. Application of inner side 3, coated with the

first component, to the part of the man's sexual organ, coated with the second component, may fix the device to the man's sexual organ."

Applicant notes that originally filed claim 8 recited (emphasis added): "The device as claimed in claim 1, wherein said glue is of the two-component type, in which said inner side is coated with a first component which is non-adhesive and in which a second component is provided to be coated on a part of the man's sexual organ, and wherein application of said inner side to said part of the man's sexual organ fixes the device to the man's sexual organ.

As a result of this second amendment to the specification (based at least on originally filed claim 8), Applicant submits that the specification provides written description support for the recitation "non-adhesive".

Applicant submits that these amendments and the associated discussions obviate the Examiner's rejection of claims 2 and 8 under 35 U.S.C. § 112, ¶ 1.

Rejection Under 35 U.S.C. § 102(b)

Applicant submits that Herr does not disclose, either expressly or inherently, every element set forth in claim 1, as amended.

Independent claim 1 recites, inter alia: "wherein the second part includes a material that is designed to rupture upon ejaculation of the second person" and "wherein the second part further includes a stiffer portion configured to be at least partially disposed in the urethra of the sexual organ of the second person".

First, Applicant submits that Herr does not disclose bladder 4 as being designed to rupture upon ejaculation. To the contrary, bladder 4 should be “fully impermeable to the constituents of seminal fluid” (Herr, c. 3/l. 53-54); upon ejaculation, bladder 4 is “extruded through the outlet which has been forced into its open position by the pressure of the enlarged bladder” (id., c. 2/l. 51-53); and the expanded bladder 4 has a volume of “approximately three-fourths of a fluid ounce” (id., c. 2/l. 51-53). Herr goes on to state that “Like condoms, the function of the present invention is to receive and contain the seminal fluid released by the male during sexual orgasm.” Id., c. 4/l. 60-62 (emphasis added). Also, because of Herr’s design, “its seminal reservoir can be made of substantially thicker material.” Id., c. 5/l. 5-6 (emphasis added). For at least these reasons, Applicant submits that not only is bladder 4 of Herr not designed to rupture upon ejaculation, but bladder 4 of Herr is designed not to rupture upon ejaculation.

Second, Applicant notes the Office Action does not allege that Herr discloses bladder 4 as being designed to rupture upon ejaculation. Instead, the Office Action states that “the elastic material of the bladder (4) is rupturable”. Office Action, p. 4. Thus, the Office Action does not even address the actual language of claim 1.

Third, Applicant submits that all materials are rupturable. Thus, in addition to not addressing the language of claim 1, the Office Action’s

statement that "the elastic material of the balder (4) is rupturable" (*id.*) merely sets up a straw man to be easily knocked down.¹

Fourth, Applicant submits that Herr does not disclose bladder 4 as including "a stiffer portion", as effectively admitted by the statement "providing the flexibility such that seminal bladder (4) [is] capable of comprising a stiffer portion and a more brittle portion . . . without departing from the scope of the invention". *Id.* (emphasis added).

Fifth, Applicant submits that the parallel language used in Herr to discuss bowl 3 and bladder 4 implies bladder 4 should be of approximately uniform thickness, rather than including a stiffer portion. When discussing bowl 3, for example, Herr states:

The bowl 3 is made from pliable sheet material such as natural or synthetic rubber such as latex rubber, soft plastic or other soft flexible material currently available in the art. The bowl is of approximately uniform thickness, preferably being between about 0.001 inch and about 0.008 inch, and most preferably about 0.005 inch. This thickness may vary depending upon the type of material used, but should be sufficient to resist tearing during the installation and use of the attachment. It is anticipated that as the condom industry continues to develop thinner stronger sheet material, this material will be applicable to the present invention.

Herr, c. 3/ll. 12-22.

Similarly, when discussing bladder 4, for example, Herr states:

The bladder is made of pliable sheet material such as natural or synthetic rubber such as latex rubber, soft plastic or other soft flexible material currently available in the art. The bladder has a thickness preferably between 0.001 and 0.008 of an inch, and

¹ Applicant notes that this same disingenuous argument was made in attempting to reject claim 1 over U.S. Patent No. 6,298,853 B1 to Blake in the Final Office Action mailed on July 26, 2007—as pointed out in the Amendment After Final Under 37 C.F.R. § 1.116 filed on September 27, 2007.

most preferably about 0.005 of an inch. However, this thickness may vary depending on the material used, but should be sufficient to render it fully impermeable to the constituents of seminal fluid, including possible disease agents such as viruses. As stated above, it is likely that future improvements in pliable sheet material for use in condoms will be applicable to the present invention.

Id., c. 3/ll. 46-57.

Sixth, even assuming, arguendo, that Herr does disclose that bladder 4 includes "a stiffer portion", Herr does not disclose that such a stiffer portion is "configured to be at least partially disposed in the urethra of the sexual organ of the second person". Moreover, Applicant submits that Herr does not disclose any portion of bladder 4 configured to be at least partially disposed in the urethra of the sexual organ of the second person.

Seventh, Applicant notes the Office Action does not allege that Herr discloses any portion of bladder 4 configured to be at least partially disposed in the urethra of the sexual organ of the second person. Instead, the Office Action appears to overlook that claim language, providing another example in which the Office Action does not address the actual language of the pending claims [claim 1 (as amended) and claim 2 (as examined)].

For at least these reasons, Applicant submits that Herr does not disclose, either expressly or inherently, every element set forth in claim 1, as amended. Therefore, Applicant submits that Herr does not anticipate claim 1 under 35 U.S.C. § 102(b).

Applicant further submits that Herr does not anticipate any of dependent claims 2-4 under 35 U.S.C. § 102(b), at least for the same reasons that Herr does not anticipate claim 1.

Rejection Under 35 U.S.C. § 103(a)

As discussed above, Herr does not disclose, either expressly or inherently, every element set forth in claim 1. For similar reasons, Applicant further submits that Herr does not teach or suggest every claim limitation in claim 1. For at least these reasons, Applicant submits that claim 1 is patentable over any proper combination of Herr and the other art of record under 35 U.S.C. § 103(a).

Applicant further submits that dependent claims 2-8 also are patentable over any proper combination of Herr and the other art of record under 35 U.S.C. § 103(a), at least for the same reasons that claim 1 is patentable over any proper combination of Herr and the other art of record.

New Claims 9-20

New independent claim 9 recites, inter alia: “wherein the second part includes a membrane that is designed to rupture upon ejaculation of the second person”.

For reasons similar to those discussed above, Applicant submits that claim 9 is patentable over Herr under 35 U.S.C. §§ 102 and 103.

Applicant further submits that dependent claims 10-20 also are patentable over Herr under 35 U.S.C. §§ 102 and 103, at least for the same reasons that claim 9 is patentable.

Request for Reconsideration and Allowance

Accordingly, in view of the above amendments and remarks, reconsideration of the rejections and allowance of each of claims 1-20 in connection with the present application is earnestly solicited.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

If necessary, the Director of the U.S. Patent and Trademark Office is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; in particular, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY, & PIERCE, P.L.C.

By _____

John A. Castellano, Reg. No. 35,094

P.O. Box 8910
Reston, VA 20195
703.668.8000

JAC/LFG/cm